DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

# ANNUAL REPORT

# OF THE

# BLOOD PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2003 through September 30, 2004

## FUNCTION

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and advises the Commissioner of Food and Drugs of its findings regarding the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

## MEMBERSHIP

A roster of members is attached.

## MEETINGS

The Committee met three times during the reporting period. Meetings were held in Gaithersburg, Maryland.

The dates of those meetings were December 11-12, 2003, March 18-19, 2004, and July 22-23, 2004.

The meeting on March 18-19, 2004 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

December 11-12, 2003: The topics included the American Association of Blood Bank's (AABB) abbreviated questionnaire, blood donor deferral for Leismaniasis, West Nile Virus, and plasma collection nomograms. FDA is considering the validity of an abbreviated questionnaire for blood donors, the impact of blood donors exposed to Leishmaniasis on the blood supply, the effect of donor testing for West Nile Virus on the blood supply, and possible adjustments in nomogram standards.

March 18-19, 2004: The topics included clinical trials for licensing Hepatitis B Immune Globulin Intravenous as a treatment to prevent Hepatitis B Virus (HBV) liver disease following liver transplantation in HBV positive recipients, supplemental testing for Human Immune Deficiency Virus (HIV) and Hepatitis C Virus (HCV), and product standards, quality assurance, and submission requirements for platelets, pheresis. FDA is currently evaluating the clinical trials for Hepatitis B Immune Globulin Intravenous, considering the effectiveness of supplemental testing methodologies for HIV and HCV, and evaluating a statistical quality control model for platelet pheresis. On March 19, the Committee held a closed session to permit discussion of personnel and program actions for the Laboratory of Hepatitis and Related Emerging Agents and the Laboratory of Bacterial, Parasitic, and Unconventional Agents. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

July 22-23, 2004: The topics were dating of irradiated red blood cells, new standards for platelet evaluation, bacterial contamination of platelets, and Hepatitis B Virus Nucleic Acid Testing for donors of whole blood. FDA is considering the viability of red blood cells and how long irradiation cells can last in order to prevent graft vs. host disease. FDA is also evaluating the recommendations from the Committee regarding platelet standards. The Committee recommendations regarding NAT testing for donors of whole blood is currently under consideration by FDA.

Detailed information related to these meetings is available in the annual report.

9/30/04
Date

Gail Dapolito for
Linda A. Smallwood, Ph.D.
Executive Secretary

# Blood Products Advisory Committee

***Chair***
**Kenrad E. Nelson, M.D.**
Expertise: Epidemiology
Term: 12/05/01 – 09/30/04
Professor
Department of Epidemiology
The Johns Hopkins University
School of Hygiene and Public Health
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***Executive Secretary***
**Linda A. Smallwood, Ph.D.**
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**James R. Allen, M.D.**
Expertise: Public Health, Epidemiology
Term: 02/08/02 – 09/30/05
President and CEO
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**Jonathan C. Goldsmith, M.D.**
Expertise: Internal Medicine, Hematology
Term: 02/13/03 - 09/30/04
Vice-President, Medical Affairs
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**Charlotte Cunningham-Rundles, M.D., Ph.D.**
Expertise: Immunobiology, Pathology
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Professor
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**Harvey G. Klein, M.D.**
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**Kenneth Davis, Jr., M.D.**
Expertise: Trauma, Critical Care Anesthesiology
Term: 02/08/02 - 09/30/05
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Professor of Surgery and Clinical Anesthesia
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**Suman Laal, Ph.D.**
Expertise: Immunology, Microbiology
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**Judy F. Lew, M.D.**
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**D. Michael Strong, Ph.D, BCLD (ABB)****
Expertise: Immunology, Hematology
Term: 02/13/03 – 09/30/04
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* Consumer Representative
** Industry Representative